HFI-35
(redacted copy)
407

Telephone: [718] 340-7000 [Ext 5301]

WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

SEP 1 5 1997

Robert L. Bard, M.D.
121 East 60th Street
New York, New York 10022

Re: 71-NYK-97

Dear Dr. Bard:

Your facility was inspected on August 11, 1997 by a representative of the New York City Bureau of Radiological Health, acting in behalf of the Food and Drug Administration. This inspection revealed that your facility failed to comply with certain of the Quality Standards for Mammography (Standards) as specified in Title 21, Code of Federal Regulations (CFR), Part 900.12, as follows:

[redacted] medical physicist, did not meet the requirement of being licensed or approved by a State, or being certified by any of the approved boards.

The specific deficiency noted above appeared under the Level 1 heading of your MQSA Facility Inspection Report, which was issued after the close of the inspection. This deficiency may be symptomatic of serious underlying problems that could compromise the quality of mammography at your facility.

In addition, your response should address the Level 2 noncompliance that was listed on the inspection report provided to you after the close of the inspection. This Level 2 noncompliance is:

Phantom image test results were not recorded for 4 months for your [redacted] mammography unit.

It is your responsibility to ensure adherence to each requirement of the Mammography Quality Standards Act of 1992 (MQSA) and FDA's regulations. You are responsible for investigating and determining the cause of the deficiencies that the inspection identifies and promptly initiate permanent corrective actions.

If you fail to promptly correct these deficiencies, FDA may, without further notice, initiate regulatory action. Under MQSA, FDA may:

impose civil money penalties on a facility of up to $10,000 for each failure to substantially comply with, or each day of failure to substantially comply with, the Standards;

suspend or revoke a facility's FDA certificate for failure to comply with the Standards;

seek an injunction in federal court to prohibit any mammography activity that constitutes a serious risk to human health.

Please note that FDA regulations do not preclude the City from enforcing its own mammography laws and regulations. In some cases, these requirements may be more stringent than FDA's. When you plan your corrective actions, therefore, you should consider the more stringent City requirements, if any.

Within 15 working days after receiving this letter, you should notify FDA in writing of:

the specific steps you have taken to correct all of the violations noted in this letter;

each step your facility is taking to prevent the recurrence of similar violations;

also, please submit sample records that demonstrate proper recordkeeping procedures, if the noncompliances that were found related to quality control or other records.

If your facility is unable to complete the corrective action within 15 working days, you should state the reason for the delay and the time within which the corrections will be completed.

Please send the original copy of your response to me at the above address, and a copy to Mr. Murray L. Kurzman of my staff at U. S. Food and Drug Administration, 6800 Jericho Tpke., Suite 109E, Syosset, N.Y. 11791. Also, send a copy to the City radiation control office that conducted the inspection referenced in this letter. You may choose to address both FDA and City requirements in your response.

If you have any questions, regarding this letter or how to ensure you are meeting MQSA standards, please call Mr. Kurzman at (516) 921-2035.

Sincerely yours,

Brenda J. Holman
District Director
U. S. Food and Drug Administration
New York District

BJH:bb

cc: Jim Potter
Director, Government Relations
American College of Radiology
1891 Preston White Drive
Reston, VA 22091

cc: Dorothy Pender
New York City Bureau of Radiological Health
2 Lafayette Street
New York, N.Y. 10007